Subpart B—Generally Licensed Items

Subpart C—Specifically Licensed Items

Subpart D—Sealed Source and Device Registration

Subpart E—Violations

AUTHORITY: Atomic Energy Act of 1954, secs. 81, 161, 170H, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2210h, 2231, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note.

EDITORIAL NOTE: Nomenclature changes to part 32 appear at 79 FR 75739, Dec. 19, 2014.

§ 32.1 Purpose and scope.

(a)(1) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution to:

(i) Persons exempted from the licensing requirements of part 30 of this chapter, or equivalent regulations of an Agreement State, or

(ii) Persons generally licensed under part 31 of this chapter or equivalent regulations of an Agreement State.

(iii) Persons licensed under part 35 of this chapter.

(2) This part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of a licensee or another, and regulations governing holders of such licenses.

(3) This part prescribes certain requirements governing holders of licenses to manufacture or distribute items containing byproduct material.

(4) This part describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed sources or devices containing sealed sources.

(b) The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of part 30 of this chapter apply to applications, licenses and certificates of registration subject to this

part, and the provisions of part 37 of this chapter apply to applications and licenses subject to this part.

(c)(1) The requirements in this part, including provisions that are specific to licensees, shall apply to Government agencies and Federally recognized Indian Tribes with respect to accelerator-produced radioactive material or discrete sources of radium-226 on November 30, 2007 except that the agency or Tribe may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and radioactive drugs and sources and devices to medical use licensees, until the date of the NRC's final licensing determination, provided that the agency or Tribe submits a new license application for these activities on or before December 1, 2008 or an amendment application for these activities on or before June 2, 2008.

(2) The requirements in this part, including provisions that are specific to licensees, shall apply to all persons other than those included in paragraph (c)(1) of this section with respect to accelerator-produced radioactive material or discrete sources of radium-226 on August 8, 2009, or earlier as noticed by the NRC, except that these persons may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and to sell or manufacture radioactive drugs and sources and devices to medical use licensees until the date of the NRC's final licensing determination, provided that the person submits a license application within 12 months from the waiver expiration date of August 7, 2009 or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever is earlier; or that the person submits an amendment request within 6 months from the waiver expiration date of August 7, 2009 or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

[30 FR 8192, June 26, 1965, as amended at 52 FR 27786, July 24, 1987; 63 FR 1896, Jan. 13, 1998; 72 FR 55928, Oct. 1, 2007; 77 FR 43690, July 25, 2012; 78 FR 17006, Mar. 19, 2013; 80 FR 74979, Dec. 1, 2015]

§ 32.2 Definitions.

As used in this part:

Committed dose for the purposes of this part means the radiation dose that will accumulate over time as a result of retention in the body of radioactive material. Committed dose is a generic term for internal dose and must be calculated by summing the projected dose over the 50 years after intake for all irradiated organs or tissues multiplying the doses to individual organs and tissues by applicable tissue weighting factors.

Dose commitment means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

Lot Tolerance Percent Defective means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

Nationally tracked source is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E to part 20 of this Chapter. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.